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PATENT APPLICATION

DISPOSABLE TRANSDUCER SEAL

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DISPOSABLE TRANSDUCER SEAL

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The subject matter of the present application is related to that of the following applications each of which is being filed on the same day as the present application: 10/_____, entitled "Medical Device Inline Degasser" (Attorney Docket No. 02356-000500US); 10/_____, entitled "Articulating Arm for Medical Procedures" (Attorney Docket No. 02356-000600US); 10/_____, entitled "Acoustic Gel with Dopant" (Attorney Docket No. 02356-000800US); 60/_____, entitled "Position Tracking Device" (Attorney Docket No. 021356-000900US); 60/_____, entitled "Ultrasound Therapy with Hood Movement Control" (Attorney Docket No. 021356-001100US); 60/_____, entitled "Systems and Methods for the Destruction of Adipose Tissue" (Attorney Docket No. 021356-001200US); 60/_____, entitled "Component Ultrasound Transducer" (Attorney Docket No. 021356-001300US); the full disclosure of each of these applications are incorporated herein by reference.

STATEMENT AS TO RIGHTS TO INVENTIONS MADE UNDER FEDERALLY SPONSORED RESEARCH AND DEVELOPMENT

[0002] NOT APPLICABLE

REFERENCE TO A "SEQUENCE LISTING," A TABLE, OR A COMPUTER PROGRAM LISTING APPENDIX SUBMITTED ON A COMPACT DISK.

[0003] NOT APPLICABLE

BACKGROUND OF THE INVENTION

[0004] 1. Field of the Invention. The present invention pertains to a sealing device for retaining degassed water within an ultrasound transducer housing.

BRIEF SUMMARY OF THE INVENTION

[0005] 2. Description of the Prior Art. Ultrasound transducers require a coupling medium to connect the transducer to a patient in order to prevent the reflection and refraction of ultrasound waves when those waves cross a border between densities of two objects. One

of the biggest issues in coupling transducers to a patient either for a diagnostic ultrasound device, or a therapeutic ultrasound device, is the presence of air. Coupling agents are used to eliminate large scale air bubbles between the transducer and the patient. For diagnostic purposes, mineral oils, hydro-gels and even water can be used to couple a transducer to a patient. In therapeutic procedures the coupling agent should be more strictly controlled so that even minute air bubbles are eliminated.

[0006] In high intensity focused ultrasound (HIFU) procedures the need to couple the transducer to the patient often includes a means of cooling the face of the transducer, or cooling a patient's skin, with a medium that will pass ultrasound energy with little or no attenuation or adverse effect. Typically this medium is water held within a transmission cavity with a cap or membrane, and through which the ultrasound energy passes.

[0007] One major issue with such a system arises from bubble formation caused by dissolved gasses being drawn out of solution. These bubbles provide an impedance mismatch to the ultrasound energy, causing reflections and localized heating, leading to observed effects such as reduced effectiveness of therapy, the destruction of the cap or seal, or patient skin burns.

[0008] Atmospheric water for example, contain approximately 8.5 PPM (parts per million) O_2, and 14.5 PPM N_2 as well as other dissolved gasses. Using dissolved oxygen (DO) as an indicator (by partial pressures the relative contents of other gasses, CO_2, CO, N_2, etc... can be calculated) it is necessary to reduce the DO to less than 5 PPM in order to reduce the attenuation effects to a manageable level.

[0009] The common method used by the industry is to prepare the fluid by passing it through a filtration and de-ionisation process to remove impurities and particulates that may precipitate out, contaminate or provide nucleation sites for bubbles. The coupling fluid is then degassed to some minimum level before introduced into the system. Typically degassing is performed by bulk cavitation under a vacuum or boiling at atmospheric or sub atmospheric pressure and then sealing the degassed fluid in a container.

[0010] In a completely sealed system the dissolved gas content will remain constant, but as described below the gas content will strive to meet equilibrium with the partial pressure of the local atmospheric conditions. During short procedures or low power ultrasound procedures the re-gas rate is usually slow enough not to cause problems. In longer procedures and/or at higher powers, the probability that re-dissolved gas will be drawn into the fluid, and

subsequently interfere with ultrasound transmission, goes up considerably since it is impossible to prevent gas diffusing through the system lining, joints and seals without investing in prohibitively expensive parts and materials.

[0011] The methods by which gasses come out of solution or enter the cooling system are various, some examples of the more common range from pressure changes within the cooling system caused by physical restriction or atmospheric conditions. Local pressure changes such as rectified diffusion from HIFU or temperature changes will bring gas out of solution as will displacement of the partial pressure of one gas by another, or by material leaching. Other methods by which gas may enter the system include diffusion through the tubing, seals and structure of the cooling system in the same way a balloon deflates, trapping micro bubbles within the surface structure and pockets of the cooling system, chemical reactions between materials in the cooling system, or as a by product of bacterial growth within the cooling system.

[0012] Precautions such as using low permeability materials for the tubing are regularly employed, but even with such precautions, the re-gas rate can become a major issue. Other methods used to reduce the effects of re-gassing include the introduction of surfactants or wetting agents to prevent bubble formation, using larger volumes of fluids, and the use of hydrophilic and/or hydrophobic polymers such as Polyvinaylpyyolidone (PVP). Experimental testing has shown these provide only a short term solution.

[0013] Numerous examples in the prior art show differing solutions to the problems of dealing with coupling HIFU transducers to a patient as well as providing an apparatus for degassing a fluid. However there has been thus far nothing demonstrating the feasibility or utility of an in line degassing mechanism combined with a HIFU therapy system during an actual medical procedure or application. The use of an inline degasser during a procedure mandates the use of a transducer housing having a cavity where the cooling/coupling fluid may circulate around the transducer. To prevent the coupling fluid from escaping the cavity, a seal is needed.

[0014] The inability of the prior art to maintain a controlled dissolved gas content in a cooling fluid over a prolonged procedure acts as a forced limitation to prolonged HIFU therapy.

[0015] Thus there remains a need for a seal capable of retaining a degassed coupling fluid for use in a HIFU procedure within a cavity containing a HIFU transducer.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] It is an objective of the present invention to provide for a seal that is both inexpensive to manufacture, and that can be quickly and easily installed into a transducer housing.

[0017] It is a further object of the invention to make a seal that is disposable so reuse and sterility issues need not be an issue.

[0018] These objectives are provided for in a disposable transducer seal that comprises a membrane that is substantially transparent to ultrasound energy. The membrane is non-porous to water and acoustic coupling fluids. A retainer has an annular configuration. There is also a means to mate the retainer with a transducer housing.

DETAILED DESCRIPTION OF THE INVENTION

[0019] The device of the present invention is a disposable transducer seal (seal). The seal is designed for use with a system for the reduction in adipose tissue. The seal comprises a membrane, a retainer and a means for attaching the seal to a transducer housing. The transducer housing is shaped similar to an inverted cup having a gap space for degassed water. The seal is used to retain the degassed water in the gap space without the water spilling onto a patient during an ultrasound procedure. The seal is intended to provide both an air tight seal, and a barrier to prevent cross contamination of the different fluids on opposite sides of the membrane.

[0020] The membrane is composed of a compound being essentially or substantially transparent to ultrasound energy. The membrane may be composed of naturally occurring materials such as latex rubber, or a synthetic material like a thin film plastic or rubber. Thermoforming plastics produce good membranes since the thickness of the membrane tends to be uniform. Uniformity in the membrane of the seal reduces scattering of the ultrasound signal during a procedure. A thermoforming polyimide provides a good example. For manufacturing considerations and for optimal performance, the synthetic polyimide is preferred. The membrane may be flexible or inflexible as long as it is drawn taunt about the retainer. While the membrane may be inflexible, it is preferred the membrane be a little flexible so that it can conform to the curves of a patients body more readily. Some flexibility also allows the membrane to respond to fluid pressure changes during procedures. This responsiveness during a procedure helps maintain a constant pressure environment for the

fluid, since the membrane may expand a little or contract a little due to variations in pressure in the system. The membrane serves as an acoustic window, so it is desirable that the membrane is substantially transparent to ultrasound energy. Smoothness in its surfaces during manufacturing will help reduce signal scattering or attenuation, thus improving performance of the membrane. A plastic membrane having desirable acoustic properties is required, and if that plastic is thermo-formable it allows for a greater uniform thickness in the manufacturing of the membrane. Uniform thickness also helps to reduce signal scattering or other loss of the ultrasound signal passing through the membrane.

[0021] The retainer may be assembled from any medically approved material. However since the retainer may be in direct contact with the patient, it is preferred to be made of a material that is easily formable (such as an extruded plastic, or moldable plastic) so that the sealing device may be discarded after a single use. The membrane is drawn taunt over the retainer, or drawn taunt and the retainer is placed down about the membrane so that the membrane remains taunt during a medical procedure.

[0022] The seal has a means for mating with a transducer housing. The means may be such as the retainer is shaped as an interlocking ring with the transducer housing having a conforming receiving aperture. Or the transducer housing may have clips for latching on to tabs on the retainer. Other means of mating to the transducer include a magnetic lock, a screw in pin, a temporary adhesive, an interference fitting male and female part (one being on the retainer, the corresponding part on the transducer housing).

[0023] The retainer may also include a means for identifying the sealing device to the transducer housing, or its attached ultrasound system. The means may be an electronic device such as an encoded chip or flex circuit, or it may be linked to the mating means, such that if the mating is not properly done the transducer housing and corresponding ultrasound system will not recognize the retainer and therefore remain in a safe mode.

[0024] Either the membrane or the retainer may also have a clear window. The window is a small gap space designed to correspond to the location of an optical emitter and photo-optical receiver such that an acoustic gel having a safety dopant can be detected by the transducer housing or ultrasound system through the sealing device.

[0025] Referring now to the drawings, Figure 1 illustrates several possible designs. The retainer 592 of the disposable transducer seal 590 has an annular configuration. The membrane 594 is drawn tightly around the retainer 592. Regardless of the material

construction of the membrane, it is necessary for the membrane to be drawn tightly about the retainer and held in place. Thus if the membrane is a polymer formed into a thin layer, or a softer latex rubber, the retainer serves to maintain the shape and rigidity of the membrane during use. If the membrane is a softer material, such as a latex rubber, then the retainer serves to keep the membrane taunt. Preferably the membrane has no slack in it, so there is no play or deformation of the membrane during use. A limited amount of deformity is desirable so the membrane can flex slightly to be concave or convex relative to the transducer. However ripples in the membrane material, folds or even a somewhat flimsy shape to the membrane may have adverse effects on the transmission of ultrasound energy during a procedure. The configuration is a circular ring, square, rectangle or other loop as required to seal a transducer housing. Thus the annular configuration depends on the aperture of the transducer housing the seal must mate with. The precise shape will vary from one transducer housing to another. The shapes shown are merely illustrative and not to be taken as limiting in any sense.

[0026] Fig. 2 illustrates a cross section of the sealing device. As can be seen the membrane is drawn tightly either within the retainer (Fig. 2A) or across the surface face of the retainer (2B). Optional elements include the encoder chip 596 illustrated in both drawings.

[0027] Fig. 3 illustrates the mating of the seal 590 to a transducer housing 500. The housing is shaped similar to an inverted cup containing an electronics and motor assembly for moving and controlling the transducer and any additional electronic components that may be integrated into the housing. The seal 590 is placed over an open aperture on the transducer housing. The design of the transducer housing is such that the transducer is placed aperture end toward the patient, and the transducer can abut the skin of the patient. The transducer housing may be used in two modes. One of those modes involves the use of degassed water circulating about the transducer within the transducer housing. A seal is needed in this mode of operation to prevent the degassed water from leaking out, and to prevent air from leaking in.

[0028] The seal is mated to the transducer housing. The mating means may be any number of mechanical connections that allow for the air and water tight seal described above. Once the seal is in place, the cavity in the transducer housing may be flooded with degassed water without water escaping. The seal may also have an electronic or mechanical recognition device such that the transducer housing will recognize the proper placement of the seal and

move the ultrasound machine from a safe mode to an active mode. Furthermore an optical window may be placed either in the membrane or in the retainer so that any kind of optical sensor or safety device using an optical sensor may still detect the proper safety material across the seal.

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